

US EPA ARCHIVE DOCUMENT



**U.S. Environmental Protection Agency
Office of Pesticide Programs (OPP)**

**EPA Internal Guidance:
Guidelines for Active Ingredient Reference Statements on Me-Too
Product Labels**

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Guidelines for Active Ingredient Reference Statements on Me-Too Product Labels

Product Referenced:

- The reference statement must be true and not easily misinterpreted.
- The active ingredient(s) in the statement must be the same active ingredient(s) found in both the me-too product label being amended and the product being referenced.
- The product being referenced on the me-too product label should be the product cited as being either identical or substantially similar to it in the me-too application.
 - For a product to be “substantially similar” to another product, its composition and labeling must be very similar to that of the other product. Substantially similar products are those that have the same active ingredients(s), but the percentages of each may vary as long as they fall within the range of composition of the referenced product and the hazards associated with the difference are not different from the referenced product. The substantially similar products must contain identical or substantially similar uses.

For example, if the product “GenericSpray” has cited the product “NameBrand” in the application for being registered as a me-too, then the “NameBrand” product can be referenced on the label of the “GenericSpray” product.

Placement:

The statement may only be placed in an area on the label that does not conflict with other required label statements. One acceptable place would be near the product brand name. An unacceptable place for the statement would be in or near the precautionary statements, the environmental hazards, or directions for use section.

Disclaimer:

The label needs to contain an appropriate disclaimer stating that the generic, me-too product “is not manufactured or distributed by” the registrant or marketer of the referenced or “brand-name” product. This disclaimer must be placed in the same area of the label so that both the statement and disclaimer can be viewed together. For example, the comparison statement cannot be placed on the front panel and the disclaimer on the back.

It is the registrant’s responsibility to use the correct trademark and copyright symbols.

Font Size:

The point type size of the statement shall not be greater than that of the Signal Word (see 40 CFR 156.60 (b)).

Font Type:

The Brand Name referenced must not be more conspicuous than the rest of the statement. Therefore, the entire statement must be in the same point type size and type without bold or highlighting.

For example, the following would be unacceptable:

- Contains dinitro-chickenwire, the active ingredient used in
NameBrand[®] (different point size)
- Contains, dinitro-chickenwire, the active ingredient used in NameBrand[®]
(different font type)
- Contains dinitro-chickenwire, the active ingredient used in NameBrand [red
color][®]
(different font color)

This is acceptable:

- Contains dinitro-chickenwire, the active ingredient used in NameBrand[®].

Submitting Label Changes:

Submit as label amendments all labels for which a statement is added that references the active ingredient of another product. Such reference statements cannot be added via notification.

Include a copy of the pesticide product label of the product the me-too is identical or substantially similar to in the amendment application.